REMARKS

In the Office Action dated March 24, 2006 the Examiner requested restriction to one of the following inventions under 35 U.S.C. 121:

> Group I: Claims 32, 33, 41 and 42, drawn to an article of manufacture and a dose form;
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> Group II: Claims 1-12 and 25-28, drawn to a method for treating a condition characterized by or involving, or that may be relieved in any measure by ameliorating, decreased β-cell mass and/or decreased β-cell number and a method of treating a disease, disorder or condition that is mediated in whole or in part by β-cells or β-cell dysfunction;
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> Group III: Claims 13-18, drawn to a method for increasing or maintaining β-cell mass and/or β-cell number;
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> Group IV: Claims 19-24, drawn to a method for stimulating growth in β-cell proliferation and/or increased β-cell mass;
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> Group V: Claims 29-31, drawn to a method of increasing insulin secretion in a subject;
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> Group VI: Claims 34-40, drawn to a method of making a medicament;
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> Group VII: Claims 43-58, drawn to a method of treating an injury or wound and a method of enhancing wound healing;
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> Group VIII: Claims 59 and 60, drawn to an improved method of treating a condition in a subject;
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> Group IX: Claim 61, drawn to administration of a composition;
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> Group X: Claims 62 and 63, drawn to a method of increasing insulin secretion in a subject; and
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> Group XI: Claims 64 and 65, drawn to a method of improving the immune function in a subject.

Applicants hereby provisionally elect Group III, claims 13-18, with traverse. Applicants respectfully submit that claims 1-65 are sufficiently related to be properly examined together and without undue burden on the Examiner. Applicants direct the Examiner's attention to MPEP § 803, which provides that there are two criteria for a proper requirement for restriction between inventions:

> (A) The inventions must be independent (see MPEP § 802.01, § 806.06, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(j)); and

> (B) There would be a serious burden on the examiner if restriction is not required (see MPEP § 803.02, § 808<, and § 808.02).

The significance of both criteria is made further clear by the M.P.E.P. § 803:

> If the search and examination of all the claims in an application can be made without serious burden, the examiner **must** examine them on the merits, even though they include claims to independent or distinct inventions [emphasis added].

Applicants respectfully submit that the Examiner has not provided a *prima facie* case in support of restriction. The term "independent" means that there is no disclosed relationship between the two or more subjects disclosed in the application. That is, they are unconnected in design, operation, or effect. MPEP §802.01. As here, it is rare that this can form the basis of a proper restriction requirement as two completely unconnected inventions are generally not recited in a single application. The inventions of pending claims 1-65 have a common focus in that the claims are related to preptin and uses thereof.

In the Office Action mailed March 24, 2006 (see page 3), the Examiner appears to assert that Invention VI was unrelated to Inventions II-V and VII-XI, that Inventions I and VI were unrelated, and that Invention I was unrelated to Inventions II-V and VII-XI. Applicants note that the Examiner has given no concrete reasons for his position.

Inventions I to XI are directed to preptins, preptin analogs, preptin agonists, salts thereof and derivatives thereof and their uses. Accordingly, Applicants submit that inventions I-XI are related.

When two or more inventions are related, then restriction is proper only if they are also distinct from each other. In the Office Action mailed March 24, 2006 at page 4, the Examiner stated that "[i]nventions II-V and VII-XI are directed to related methods using preptins, analogs, agonists, derivatives and salts thereof." Applicants direct the Examiner's attention to MPEP 806.5, which states:

> To support a requirement for restriction between two or more related product inventions, or between two or more related process inventions, **both two-way distinctness and reasons for insisting on restriction are necessary**, i.e., separate classification, status in the art, or field of search. See MPEP § 808.02. See MPEP § 806.05(c) for an explanation of the requirements to establish two-way distinctness as it applies to inventions in a combination/subcombination relationship. For other related product inventions, or related process inventions, the inventions are distinct if
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> > (A) the inventions *as claimed* do not overlap in scope, i.e., are mutually exclusive;
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> > (B) the inventions *as claimed* are not obvious variants; and
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> > (C) the inventions *as claimed* are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 802.01 [emphasis added].

Thus, if the inventions are related, the Examiner has the burden of showing that the claimed inventions are mutually exclusive and are not obvious variants, and are either not capable of use together or can have a materially different design, mode of operation, function, or effect. Applicants respectfully submit that the Examiner has not met this *prime facia* burden because the Examiner has not set forth any concrete reasons as to why the methods in groups II-V and VII-XI would be mutually exclusive.

Even if the Examiner were to establish that the inventions were distinct as set forth in M.P.E.P. §802.01, Applicants further respectfully submit that that the search and examination of all the claims in the application can be made without serious burden. All 11 claim Groups are drawn to preptin and uses thereof. Applicants believe preptin to be a previously unknown and uncharacterized, pancreatic islet beta-cell hormone. Accordingly, Applicants submit that a search and examination of all pending claims would not be a serious burden on the Examiner.

The first paragraph on page 5 of the March 24, 2006 Office Action states that "[t]he search for each of the above inventions is not co-extensive particularly with regard to the non-

patented literature search." However, no reason was given to support this contention, nor why the Examiner has focused in on the non-patented literature search.

In sum, Applicants respectfully submit that there would be no serious burden on the Patent Office to search the art with regard to the inventions of claims 1 through 65, nor has the Examiner provided rationale as to why it might be a burden. Thus, Applicants request that the restriction requirement be reconsidered and withdrawn.

Should the Examiner maintain the restriction requirement that not all of Groups I through XI can be examined together, Applicants request, at a minimum, that the Examiner reconsider the restriction requirement and reformulate it so that Groups II, III, IV, and V are joined together for the reasons set forth above. Applicants submit that the Examiner has found that these inventions to be related and has not set forth a *prima facia* case that the inventions were distinct. Further, a search and examination of these pending claims would not be a serious burden on the Examiner.

Alternatively, should the Examiner maintain restriction and consider that not all of Groups II through V could be examined together, Applicants request, at a minimum, that Groups II, III, and IV be re-joined for examination for reasons set forth above, including that the Examiner has found that these inventions to be related and has not set forth a *prima facia* case that the inventions are distinct. Applicants note that Inventions II, III and IV are directed to methods of treatment using preptins, preptin analogs, preptin agonists, salts thereof or derivatives which relate to conditions related to ß-cell mass or number. Further, a search and examination of these pending claims would not be a serious burden on the Examiner.

As noted above in this Response, in order to comply with 35 U.S.C. 121, Applicants provisionally elect, with traverse, Group III, claims 13-18.

In the Office Action mailed March 24, 2006, the Examiner also stated that claims 1-65 were generic to patentably distinct species and has required election of a single disclosed species. In response, Applicants provisionally elect, with traverse, human preptin as found, for example, in SEQ ID NO: 1. In support of their traverse, Applicants respectfully submit that all species could be searched and examined without serious burden on the Examiner. As stated earlier, Applicants believe preptin to be a previous unknown and uncharacterized, pancreatic islet beta-cell hormone. Accordingly, Applicants submit that a search and examination of all species of preptin, including analogs, derivatives and agonists, would not be a serious burden on the Examiner. Applicants request that the Examiner expand his search upon a finding of allowable species.

At present, claims 1-3; 5-8; 13-15; 17; 19-21; 23; 25-36; 38; and 40-65 are readable on the provisionally elected species. Applicants request that the search be expanded upon finding of an allowable species.

CONCLUSION

For the reasons set forth above, Applicants request that the Examiner reconsider the restriction requirement and that pending claims 1 through 65 be examined. Should the Examiner maintain the restriction requirement that not all of Groups I through XI can be examined together, it is requested, at a minimum, that the Examiner modify his restriction requirement and that Groups II, III, IV, and V be examined together. Should the Examiner hold that not all of Groups II through V can be examined together, it is requested that the restriction requirement be modified so that Groups II, III, and IV are examined together.

Also, in response to the Examiner's requirement of election of a single disclosed species, applicants have provisionally elected, with traverse, human preptin such as that exemplified by SEQ ID NO: 1.

Applicants note that, as required, they have provisionally elected the invention of Group III and the species of human preptin, both with traverse.

The Examiner is encouraged to contact the undersigned if it is believed this would expedite prosecution.

Respectfully submitted,

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